Analysis of Expansion of Access to Care Through Use of Telemedicine

REPORT 4: STUDY SUMMARY AND RECOMMENDATIONS FOR FURTHER RESEARCH

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EXECUTIVE SUMMARY

This is the fourth report under a contract with the Health Care Financing Administration to study telemedicine and mobile health services. The general objectives of this project were to: 1) assess the safety and effectiveness of telemedicine as a means of health care delivery, and 2) recommend options for policies regarding payment, utilization review, and quality assurance. Early in the project, it was determined that the primary focus of the study should be telemedicine. Consequently, mobile health services were addressed only in Report 1.

This report provides an updated summary of the work completed to date, and presents recommendations regarding further research. Toward this latter end, we discuss the major research questions to be addressed, and suggest a broad evaluation strategy for telemedicine. We also propose that particular attention be given to specific aspects of research design in the study of telemedicine.

The first phase of this project involved a comprehensive search of the literature on telemedicine and mobile health services. Our study of extant research yielded a significant body of data pertaining to the effectiveness of teleradiology, and to a lesser extent of telepathology, but we found very little research addressing the effectiveness of other consultative uses of telemedicine. The published data available were insufficient to support telemedicine as an effective means of health care delivery. There was no evidence that telemedicine is, or is not, cost-effective.

The second phase of the project involved a series of eight case studies of telemedicine programs. The purpose of this phase was to assess the current status of telemedicine, and to ascertain whether the site visits might provide data on effectiveness. In addition, we conducted phone interviews with directors of several other telemedicine facilities. We concluded that there are many areas in which telemedicine is medically effective, and that it has the capacity to provide good quality medical care to patients who might otherwise have limited access to such services.

In conjunction with the literature review and site visits, we developed a taxonomy of telemedicine applications and an analytic framework for assessing effectiveness. These are described in detail in Reports 2 and 1, respectively. As we learned more about telemedicine over the course of this project, and in response to suggestions by the project's technical advisory panel, we made minor modifications in the taxonomy and framework, which are discussed in the current manuscript. We suggest that the taxonomy may be a useful mechanism for classifying telemedicine applications for health services research, and that the analytic framework might be useful for clinical research.

The third phase of this project involved a study of quality assurance, utilization review, and payment policy. Many telemedicine applications are widely accepted as effective, and we concluded that reimbursement for those services is appropriate. Certain applications, however, will require additional research. A detailed discussion of our recommendations is in Report 3. We also recommend the development of a set of empirically-derived utilization guidelines that might give direction to those who wish to determine whether telemedicine is being used appropriately, thus limiting under-utilization as well as over-utilization.

The final chapter of the present report includes a discussion of research needs in telemedicine. We recommend a general strategy for assessing the effectiveness and the effects of telemedicine, and suggest that studies be conducted to investigate various policy options. We propose certain approaches to research design that might maximize the quality of the information obtained from any proposed research.

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CHAPTER 1

INTRODUCTION

A. PROJECT AND REPORT OVERVIEW

1. Project Overview

The original purpose of this project was to examine available information on the expansion of access to care through the use of telemedicine and mobile health services. Early in the project, it was decided that telemedicine should be the exclusive focus. The primary project objective was to examine issues related to the development of a Medicare coverage policy for such services. The major consideration was whether services provided using telemedicine technologies are medically safe and effective.

The approach to the project involved literature review, development of a conceptual framework for the analysis of studies examining effectiveness, selected case studies, review of coverage policies of private third-party payers, and examination of utilization review and quality assurance/improvement models currently in operation as part of existing telemedicine systems.

Three reports have been written prior to this one. Report 1 (Grigsby, Kaehny, Schlenker, et al., 1993) covered the literature review and analytic framework. Report 2 (Grigsby, Sandberg, Kaehny, et al., 1994) contained case study data and presented a taxonomic system for classifying telemedicine applications with respect to their need for further evaluation. Report 3 (Grigsby, Barton, Kaehny, et al., 1994) covered the areas of utilization review, quality assurance/improvement, and coverage policies related to telemedicine. This fourth report is intended in part to summarize and update the previous three reports.

Preparation of this final report follows a meeting of a technical advisory panel comprised of experts in telemedicine, health care policy, and health services research. Some minor revisions were incorporated in the final version of Report 3 as a function of the recommendations of members of the advisory panel. The suggestions of the panel members were also taken into account in the preparation of this fourth document. The reader of this report will not find major revisions of our previous work. Instead, the differences reflect refinements in our thinking and a shift in emphasis on certain issues. These changes were a function of the growth of our understanding of telemedicine over time, as a result of more recently discovered literature, experience gained on site visits, conversations with various individuals who are active in the field, feedback concerning our earlier work, and the input of study consultants. This report presents overall conclusions and a summary of recommended policy options.

This document also contains recommendations regarding research on telemedicine. There are currently a number of federal agencies actively involved in the funding and evaluation of telemedicine in the United States. In addition to the Health Care Financing Administration (HCFA), these include the Advanced Research Projects Agency (ARPA), Department of Defense (including separate projects initiated by the Air Force, Army, and Navy), Health Resources Services Administration (HRSA), National Aeronautics and Space Administration (NASA), National Telecommunications Infrastructure Administration (NTIA), Office of Rural Health Policy (ORHP), Rural Electrification Administration (REA), and the U.S. Congress Office of Technology Assessment (OTA). Recognizing the importance of a concerted federal approach to telemedicine, representatives of several of these agencies have attempted to develop a relatively integrated program of funding and

research. Our recommendations regarding a research agenda are intended primarily to address the needs of HCFA, but they are made in the context of a certain degree of interagency cooperation.

2. Outline of the Current Report

This is the fourth report of the project. It summarizes the information discussed at length in previous reports, with some minor revisions and additions. Chapter 1 provides background and introductory information. Chapter 2 discusses our review of the literature on telemedicine. Chapter 3 consists of a discussion of the current status of telemedicine. Chapter 4 addresses a taxonomy of telemedicine applications, and a conceptual framework for assessing the effectiveness of telemedicine technology and applications. Chapter 5 contains a summary of our recommendations regarding quality assurance, utilization review, and payment policies. Chapter 6 is a discussion of what we view as important areas for future research.

CHAPTER 2

LITERATURE REVIEW

A. DEFINITION OF TELEMEDICINE AND APPROACH TO THE REVIEW

1. Definition of Telemedicine

There is no consensual definition of telemedicine. The term has been used to refer to a range of applications that varies in its scope. For the purposes of this study we defined telemedicine as the use of telecommunications technology as a medium for providing health care services for persons that are at some distance from the provider. Others have suggested that educational programming and public health services that do not provide direct patient care may also be considered telemedicine, but we narrowed our focus somewhat in order to address more specifically the questions posed by HCFA in the agency's Request for Proposals.

We were thus concerned primarily with the transmission of images routinely used in radiology and pathology, and with the provision of clinical medical services that would ordinarily occur in a face-to-face interaction between patient and health care provider. Included in our definition were the real-time transmission of video patient examination, as well as transmission of still images, facsimiles, and data. With the exception of psychiatry, telemedicine can provide very few direct interventions, but it may be utilized for diagnosis, consultation, and patient management. To remain focused, we did not include such activities as continuing medical education, distance learning, or applications involving informatics independent of the care of specific patients.

2. Approach to Literature Review

The primary concern of HCFA was whether the literature supports the use of telemedicine as a safe, medically effective set of procedures. A medical technology that does not meet this minimal standard should not be used, and in the absence of any evidence of safety and effectiveness, it is necessary to proceed with some caution. Other questions were of interest, but were not the main focus of the project. In particular, we wished to determine the extent to which telemedicine had been shown: a) to be cost-effective, b) to improve the quality of available services, and c) to be acceptable to patients and providers.

The review covered technical matters insofar as they affect the quality of service. The exact technical specifications of the various components of telemedicine systems were of secondary importance. This reflected both the objectives of the project as outlined in the RFP and our own assumption that the available technology would be far ahead of the literature, so that published findings would probably be out of date by the time they appeared in print.

Using the Medline database, we found that approximately 50% to 60% of the relevant literature could be located. We next checked reference lists in previously identified papers. We found several additional references during a search on the Internet using different gophers and news groups, and in discussions with people involved in telemedicine.

Because of the rapid pace of technological advance, we made a decision to focus our attention on more recent publications. On technical matters (i.e., technology and medical effectiveness), we reviewed the literature for the past five to seven years. Even many studies published in the last 5 years are now out of date. We also reviewed selected studies from older literature that we considered

relevant and important. The technology of the 1960s and 1970s is obsolete, but many of the critical policy and social issues addressed during those years remain current. We reviewed the foreign literature published in English insofar as the programs studied were relevant to service delivery in the United States.

We tried to identify well-designed, carefully conducted studies, and innovative model programs. Often these were not studies of telemedicine *per se*, but of related subjects such as digitization of radiologic images. We assumed that a paper having gone through the peer-review process insures at least some kind of minimal standard of adequacy. We therefore limited ourselves primarily to papers published in scientific and professional journals. This was somewhat problematic in that much of the research in telemedicine has been published only in technical reports, or has been presented at conferences, often informally and with little rigor. Many of these papers were unavailable, and of questionable value.

The literature review was conducted at the beginning of this project. Since that time we have continued to search for new references, and while a few papers have been published in the interim, our general conclusions remain unchanged from our first report. We had anticipated that it would be possible to obtain preprints of research conducted but not yet in press during the course of this project, but in the course of our work we found scant empirical support for telemedicine, and very few research projects in progress.

The literature has many significant gaps. There is a welter of approaches and technologies, with no replications or cross-validation studies. The only unifying themes concern the use of these technologies in one or two specialty areas.

B. SUMMARY OF LITERATURE REVIEW

1. Teleradiology

The feasibility of radiology via telecommunications has been demonstrated satisfactorily. The accurate interpretation of radiographs via digital display requires scanners with high spatial and gray scale resolution. A survey of the literature suggests that, for scanning and videocameras, a 10- to 12-bit gray scale contributes significantly to diagnostic accuracy. Increased gray scale, however, is associated with increased storage requirements and slowed image transmission times (Lo, Gaskill, Krasner, and Mun, 1989). A somewhat lower contrast resolution (e.g., 8 bits) may be adequate for monitors, given the limitations of the human eye in detecting differences in gray contrast. Radiologists using interactive digital displays will need adequate training and experience with the system to use its postacquisition image enhancement and manipulation capabilities to optimal advantage.

There are some applications for which effectiveness has not been demonstrated satisfactorily. Excretory urography, for example, was found to be somewhat difficult to perform accurately (DiSantis, Cramer, and Scatarige, 1987). The technology has changed significantly in the six or eight years since data were collected for that study, and perhaps the findings would be more in the favor of telemedicine today, but that remains to be shown.

For the detection of certain kinds of pathology, digital teleradiology, using either films or interactive display, is the equal of conventional radiographs. It appears that even when digital methods show a statistically significant inferiority to analog display, the magnitude of the difference

is ordinarily not great. Exceptions to this generalization are the interpretation of chest (pneumothorax, interstitial infiltrates) and bone films (nondisplaced fractures; see Scott et al., 1993). It remains for policy makers to decide whether any decrement in accuracy is acceptable, or whether some tradeoffs with ease of access may be reasonable. Current practice is not without errors, and digital radiology should not be held to a standard that conventional radiology is not expected to meet.

The situation would be clarified by research on the effects of training on accuracy with the video monitor. If radiologists familiarized themselves with the system to the point that they understood its image manipulation procedures thoroughly, and could use them more or less automatically, perhaps differences between display modes would be minimized or eliminated.

Digitally acquired data (MR and CT images, for example) can be transmitted directly, with no need for a hard copy, with essentially no loss of information. It is only with analog films (e.g., chest radiographs) that the process of digitization may introduce problems with resolution.

The cost effectiveness of teleradiology has not been addressed in the medical literature. Occasional papers discussed the costs of specific system components (e.g., Batnitzky et al., 1990; Dwyer, Templeton, and Batnitzky, 1991; Templeton et al., 1991). Because of the rapid change in the sophistication and cost of technological innovations, however, such information is quickly obsolete. Should current trends continue, however, the cost of an acceptable, sophisticated system that meets the appropriate standards for resolution will continue to decrease.

A report published by Arthur D. Little, Inc. (1992) suggested that large savings would ensue from the use of teleradiologically transmitted images. According to their model, $1.7 million would be saved from a reduction in contract specialists' travel time. They estimated a "potential" savings of $288.2 million for the cost of images "that are either lost in the mail between health care entities or misplaced internally." Although it is widely cited, this study had some significant limitations, and in fact does not support the hypothesis that telemedicine is a cost-effective tool for delivery of medical care.

There has been some preliminary research on the acceptability of teleradiology to providers. In most cases, radiologists have expressed a preference for conventional films and view boxes. In part, this reflects the fact that less time is spent reading films than using the video monitor, and may also be a function of familiarity. Perhaps residents exposed equally to both methods from the beginning of their training will react differently. The current proliferation of intra-institution teleradiology systems permitting radiologists to take calls at home may affect these attitudes over time.

2. Telepathology

Telepathology is feasible, but research suggests that the equipment used must be somewhat more sophisticated than is the case for other applications. Accurate viewing of tissue specimens via video-microscopy appears to require a high resolution monitor, high speed data transmission medium (if one wishes to view moving images without artifact), and rapid monitor refresh rate (i.e., the speed with which images on the monitor are replaced by new images). A restricted range of tissue specimens has been used in research to date, but the findings suggest that the remote examination of frozen sections can be done with good accuracy. In one or two studies, accuracy was slightly lower than might be expected from ordinary light microscopy (approximately 5% less accurate in the 1992 paper by Eide, Nordrum, and Stalsberg).

It remains to be established whether, using adequate equipment, telepathology consistently shows lower reliability or validity than standard techniques. The 1987 paper by Weinstein and his

collaborators suggests that the two approaches may be approximately equal in effectiveness, at least insofar as the analysis of breast tissue is concerned. It should be noted that light microscopic examination of tissue samples is itself not always 100% accurate. A question for policy makers to decide is whether a tradeoff between accuracy and accessibility of services is acceptable, and if so, how large a decrement in accuracy is acceptable.

The cost-effectiveness of telepathology was not addressed in the literature. Occasional papers discussed the costs of specific system components (e.g., Martin et al., 1992), or the relative costs of system components, but these were of little value in understanding the economic impact of telepathology on health care. There was no research on the acceptability of telepatnology to providers.

3. Clinical Telemedicine Consultation

The fact that the research literature is dominated by diagnostic radiology and pathology might lead one to believe that there are few other uses for telemedicine. In fact, telecommunications technology has been used by many other specialties, although its effectiveness has not been adequately studied.

As a consequence of this lack of research, it is difficult to assess the effectiveness of clinical telemedicine, or its effects on health care delivery. For the most part, the studies that have been done have been focused on very circumscribed issues, and have been characterized by small samples. Studies have been conducted to assess the effectiveness of telemedicine for several applications, including dermatology (Murphy, Fitzpatrick, Haynes, Bird & Sheridan, 1972), cardiac auscultation (Mattioli, Goertz, Ardinger, Belmont, Cox & Thomas, 1992; Murphy, Block, Bird & Yurchak, 1973), echocardiography (Sobczyk, Solinger, Rees & Elbl, 1993), and neurology (Hubble, Pahwa, Michalek, Thomas & Koller, 1993).

Perhaps the most thorough study of telemedicine effectiveness was one conducted by Conrath, Dunn, Bloor and Tranquada in 1977. Although the technology they tested is now obsolete, the findings were nevertheless interesting. They compared color television, black and white television, black and white still images, and telephone as vehicles for primary health care consultation. Although the study methodology was limited in some respects, the authors reported finding minimal differences between the four conditions, and suggested that telephone and still images, as the least expensive alternatives, were therefore preferable.

Cost-effectiveness has never been examined in depth. Some estimates of "potential cost reductions" due to the availability of teleconferencing for remote consultations and continuing education were made in a report published by Arthur D. Little, Inc. (1992). They used data obtained from the Texas Telemedicine Project in Austin, Texas, suggesting "at least a 14% savings" over more standard medical services. According to their model, reduction in overhead and travel time are the primary sources of savings from teleconferencing (said to approximate $131.6 million per year nationally). This report has been widely cited as proof of the cost effectiveness of telemedicine. As noted in the executive summary of tuis report, however, the findings are "based on estimates and projections." Few data were available to illuminate the matter of telemedicine's possible cost effectiveness, and we remain in the dark on this issue.

At this time, statements about the cost effectiveness of telemedicine should probably be regarded as pure conjecture. Furthermore, it seems unlikely that we will really understand the relationship of costs and benefits for some time to come. There are several reasons for this, including the following: 1) Patient volumes are currently very low (Allen, 1993), and telemedicine remains something of a

novelty, essentially an appendage tacked on to a few medical institutions. If successful, telemedicine networks will eventually be integrated into the overall health care system. The study of cost-effectiveness at this time will therefore only provide data on a single program (or group of programs) at a particular time in a developing system. 2) If telemedicine actually increases access to care, total expenditures for health care will increase. It is not now clear whether telemedicine will augment, or substitute for, conventional medical care. 3) Many telemedicine programs are having significant difficulty despite adequate funding and staffing. Continuing low patient volumes result in a very high cost per unit of service, and may place many investments in telemedicine at risk. 4) The introduction of new medical technology is usually touted as cost-effective, but rarely have anticipated savings been realized. It requires going against the historical grain to expect telemedicine to be different. 5) The costs of new technology is decreasing substantially, while capacity increases. This, and the convergence of unrelated technologies with telemedicine, may produce unanticipated results that could drive costs in either direction. 6) Factors that cannot be anticipated may cause telemedicine to be "locked in" to certain technologies or applications that may be more or less efficient or costly. VHS videotape, for example, became the *de facto* standard for the video industry, despite the apparent technical superiority of the beta format, as a consequence of market forces. Similarly, interactive videoconferencing could become such a standard despite the fact that, for most applications, it is not clear that it is necessary. 7) The effects of changes in the telecommunications industry cannot be anticipated. Election year political considerations derailed efforts to amend the Telecommunications Act of 1934 in the 103rd Congress. Overhaul of the way in which the industry is regulated could have profound effects on the development and implementation of the technology. 8) Dramatically decreasing costs have the potential to make telemedicine systems more affordable. As with personal computer systems, however, decreasing costs for existing telemedicine technology may lead purchasers to acquire improved (and perhaps unnecessary) equipment rather than taking savings on equipment that is adequate for most purposes.

There is still a great deal to learn about the use of telemedicine. Although policy makers may decide that sufficient data exist to proceed with wide-scale expansion of telemedicine services, there is a clear need for carefully designed research on process and outcomes in telemedicine.

CHAPTER 3

SUMMARY OF SITE VISITS

A. RATIONALE, APPROACH, AND OBJECTIVES OF SITE VISITS

1. Rationale

The primary interest of HCFA in requesting case studies was to determine how telemedicine was being used and to obtain additional information bearing on the question of whether telemedicine is safe and effective. The purpose was not to study technical specifications in detail, but to focus on applications of telemedicine technology. Because of the diversity of telemedicine programs, we determined that it would be desirable to visit programs varying on several parameters.

The projects selected varied along the following dimensions: 1) technological sophistication (from audioconferencing to teleradiology); 2) administrative structure (Department of Defense, academic medical centers, private hospital, Canadian health care, NASA); 3) involvement in research (from none through extensive programs of clinical and basic research); 4) degree of geographic isolation (from rural states through Space Shuttle orbit and remote Pacific archipelagos); 5) range of applications; 6) source of funding (grants, appropriations, private funds, educational activities); 7) the length of time in operation (from newly begun programs through one in existence for over 20 years).

Persuasive arguments could be made for case studies at programs that were not visited, and several individuals have made such arguments. In the end, site selection was admittedly somewhat arbitrary, and we were unable to visit some highly regarded programs. Nevertheless, we believe that the case studies conducted provide a reasonable cross section of North American telemedicine facilities and programs.

2. Approach

Site visits were from one to three days in duration, depending on the complexity of each site. Visits consisted primarily of interviews with individuals involved in the various telemedicine applications. We were shown the equipment at each site, and in most cases we observed a televised consultation or review of diagnostic images. We also had the opportunity to speak with providers at remote sites, either in person or via the telemedicine interactive television (IATV) system. Most sites arranged interviews with providers who had not used or were skeptical of telemedicine, as well as those who were enthusiastic users of telemedicine.

Because it was not possible to visit many well-established telemedicine sites, we also conducted telephone interviews with several program directors whose facilities we did not visit. In particular, we were interested in obtaining data regarding costs, equipment, remote sites, staffing patterns, and medical specialties using the telemedicine system.

3. Objectives of the Case Studies

The objectives of the case studies were as follows. 1) To obtain information regarding the current practice of telemedicine. This information would include data on costs, equipment, applications, practice patterns, and acceptability of the system to providers. 2) To provide information that would permit the development of a useful taxonomy of telemedicine applications. 3) To provide a means of evaluating the adequacy of the analytic framework for assessing effectiveness that was proposed

in Report 1. 4) To expand upon the information obtained from the literature review previously completed under this contract. Most of the published literature deals with teleradiology, and only by conducting several site visits would it be possible to learn more about how telemedicine is currently being practiced. 5) To familiarize ourselves with general issues facing telemedicine, and to learn how various sites attempt to deal with these issues. Based on what we learned from the visits to established telemedicine facilities, we have tried to produce a document that might be of some assistance in the development of telemedicine programs.

B. SITES SELECTED FOR CASE STUDIES AND TELEPHONE INTERVIEWS

1. Case Study Sites

We made visits to the following eight sites, presented below in the order in which they were visited. Descriptions of the activities of these programs may be found in Report 2 (Grigsby, Sandberg, Kaehny, et al., 1994).

- Oregon Health Sciences University, Portland, Oregon
- NASA Johnson Space Center; Krug Life Sciences, Houston, Texas
- University of Kansas Medical Center, Kansas City, Kansas
- Medical College of Georgia, Augusta, Georgia
- Eastern Montana Telemedicine Project, Billings, Montana
- Tripler Army Medical Center, Oahu, Hawaii
- Memorial University of Newfoundland Health Sciences Center, St. John's, Newfoundland
- East Carolina University, Greenville, North Carolina

2. Telephone Interviews

In addition to the sites that were visited, several other telemedicine programs were surveyed by telephone. Descriptions of these programs also may be found in Report 2.

C. CURRENT STATUS OF TELEMEDICINE

1. The Current Scope of Telemedicine

Although telemedicine has come and gone in the past, this time it appears likely that it will persist and become integrated into the health care system. If it proves to be medically useful and cost-effective, telemedicine is likely to become a relatively routine, unremarkable aspect of health care delivery over the next ten to twenty years. Adequate technology is available to support many applications, costs are decreasing rapidly, there is great investor interest, and other barriers to the proliferation and growth of telemedicine systems (licensing, confidentiality, liability, regulation of telecommunications) are being addressed. The expansion of managed care programs is conducive to the spread of the technology, and may prove to be an important factor in establishing a strong foothold for telemedicine, especially since the lack of reimbursement is not a rate determining factor for HMOs and other capitated health care plans.

Nevertheless, the volume of telemedicine being done is quite low. Many well-established programs report as few as 2-5 contacts per week. Remote sites for some programs have in some cases failed to utilize telemedicine consultation at all, and in some well-funded, well-equipped programs patient volumes have been extremely low. At the beginning of 1993, there were perhaps

ten to fifteen operational telemedicine programs in the United States, excluding teleradiology. By the end of 1994, there may be as many as twenty-five or thirty such programs actively involved in providing patient care. Although estimates are difficult to make, there currently may be an additional 40 or 50 systems in various stages of development. The majority of the first wave of recent telemedicine programs was located in academic medical centers, and while such centers continue to dominate the field, telemedicine systems are being established by non-academic private hospitals, HMOs, private corporations, group practices, and investor groups.

The structure of telemedicine systems is quite variable. In only a few cases does there appear to be an interconnected system that could be described as a true network. In most cases, a program consists of a tertiary care hub and one or a few remote sites. The equipment used by different telemedicine programs is generally commercially available, and a typical telemedicine program uses interactive compressed video, 1- and 3-chip charge coupled device (CCD) cameras, a document camera, and electronic stethoscope. Most clinical telemedicine sites do not have a dedicated teleradiology system, and most teleradiology sites are not associated with clinical telemedicine programs. In many cases, for consultative purposes, scans and radiographs are placed on a conventional light box and images are transmitted by videocamera. The use of fax transmission and transmission of data by modem are common.

2. The Effectiveness of Telemedicine

The research literature does not provide unqualified support for teleradiology. As noted previously (Reports 1 and 2), the interpretation of chest and bone films remains somewhat problematic using digital radiology. The American College of Radiology (ACR) has established a set of standards for teleradiology, and research continues to be conducted in the field.

With respect to clinical telemedicine consultation, few data exist to support its effectiveness. A handful of studies have been conducted, most with small samples. In part this reflects the fact that telemedicine is a low volume enterprise, so that large scale studies have been impossible. There is currently a move to establish one or two consortia of telemedicine centers that would pool data for purposes of research, enabling investigators to obtain samples of a reasonable size. This could be a significant step in the development of a body of literature addressing both clinical and health services aspects of telemedicine. In addition, two peer-reviewed journals have been established in the past few months, both to begin publication in 1995. These are the *Telemedicine Journal* and the *Journal of Telemedicine and Telecare*. Although the scientific study of telemedicine remains immature, and the results of many current studies will not be available for some time to come, an emphasis on research is valuable.

Although the research literature is too limited to support telemedicine as effective, the information we obtained during our site visits suggested that telemedicine, with some qualifications, is effective, and that it may have significant potential for addressing problems concerning access to care. In Report 2 under this contract (Grigsby, Sandberg, Kaehny, et al., 1994), we discussed in general terms those kinds of telemedicine applications that appear to be effective.

CHAPTER 4

ANALYTIC FRAMEWORK AND TELEMEDICINE TAXONOMY

A. OVERVIEW OF ANALYTIC FRAMEWORK AND TAXONOMY

The first report under this contract contained an analytic framework for analyzing the effectiveness of telemedicine. The purpose of that framework was to identify the critical dimensions along which we proposed to examine effectiveness. At that time we had completed a review of the literature but had not yet undertaken the site visits. As a consequence, given that the literature on telemedicine is dominated by studies of teleradiology, our emphasis was shaped in particular by a concern with diagnostic accuracy.

Given that telemedicine is at this point primarily a diagnostic and consultative enterprise, an emphasis on diagnostic accuracy seems entirely consistent with the assessment of medical effectiveness. Nevertheless, the practice of telemedicine is rapidly expanding, and a rigorous evaluation of effectiveness, if undertaken at all, clearly will be conducted only after a good deal of effort and money has been invested in telemedicine systems. Furthermore, on the face of it, many telemedicine applications appear to be effective. For these applications, more intensive *post hoc* study is not inappropriate. We suggest that as new technologies and untested applications are instituted, these be subjected to closer scrutiny prior to their widespread dissemination.

Report 2 of this contract presented a taxonomic scheme for categorizing different telemedicine classifications. As we noted, there are many ways to approach this task. Perhaps the most obvious is to classify telemedicine by the specialties that are using it, but this would lead to a large number of categories and a limited capacity for generalization. The taxonomy we recommended was developed in large part on the basis of information obtained during the course of site visits. We were interested primarily in the ways in which telemedicine was being used, and only secondarily in the specialties using telemedicine. Consequently, the classification system we proposed was based on various *processes* of care rather than on specific organ systems, and on the status of specific applications in relation to current research needs.

In this final report we describe two different taxonomies. The first, previously described in Report 1, is a more general approach to classification that is a function of the degree to which different uses of telemedicine have been demonstrated to be effective or probably effective. The second taxonomy is based strictly on processes of care without regard to whether effectiveness has been established. This second taxonomy is described below.

B. TAXONOMY OF TELEMEDICINE APPLICATIONS

1. Summary of the Original Taxonomy

The original taxonomy we developed consists of four categories of telemedicine applications. The first group consists of applications that are plainly effective. They can be readily defined, and their implementation would be relatively straightforward. Included are such services as emergency evaluation of patients and medical/surgical followup. The second group consists of applications that are likely to be effective, but the implications of implementing programs in these areas are unclear. They would require a certain amount of health services research before we really understand their

impact on the health care delivery system. Included are such services as the short-term management of self-limited conditions, or chronic disease management. The third group consists of applications for which the safety and effectiveness are currently unknown, or for which basic research is required to specify requisite technical parameters. This could include technically challenging applications for which audio or visual standards have not yet been established, such as interpretation of chest radiographs. The fourth group consists of applications that are at this point entirely experimental, or which anticipate the integration of different existing advanced technologies. The use of robotics, virtual reality, three-dimensional imaging, neural networks, and other applications of artificial intelligence fall in this category. A detailed discussion of the taxonomy may be found in Reports 2 and 3.

2. Telemedicine Taxonomy Based on Processes of Care

In developing the taxonomy described here, we were interested primarily in the ways in which telemedicine is utilized, and only secondarily in the specialties using telemedicine. We were not concerned with whether the effectiveness of these demonstrations has been demonstrated. Furthermore, we did not address uses that were strictly educational, such as continuing medical education or graduate nursing training. This classification system therefore is based solely on various *processes* of health care rather than on specific organ systems. We suggest that this approach would be especially useful in the conduct of health services research on telemedicine. The categories are as follows.

1) *Initial urgent evaluation of patients, triage decisions, and pretransfer arrangements.* These might include emergency neurosurgical, cardiac, or trauma consultation. They would be one-time consults involving a specialist, the patient, and a primary care provider at a remote site.

2) *Medical and surgical followup and medication checks.* These might include postsurgical followup care between the specialist and patient, either with or without the primary care provider present depending on the purpose of the consult. Psychiatrists might use telemedicine for medication checks with established patients.

3) *Supervision and consultation for primary care encounters in remote sites where a physician is not available.* These would consist of one-time consults with a primary care physician on one end and a nurse practitioner or physician assistant with the patient at a remote site.

4) *Routine diagnostic evaluations based on history, physical findings, and available test data.* These are one-time consults which may involve a physician, nonphysician provider, or only the patient at the remote site. Psychiatric evaluations, for example, might include only the psychiatrist and patient.

5) *Transmission of diagnostic images.* Orthopedic consults may not require that the patient be present in many situations, in which case live videoconferencing would not be required. Applications in this category might simply involve the transmission of static images, as would be the case for most radiology. A store and forward system might be used, although applications in this category might also include regularly scheduled clinics.

6) *Extended diagnostic work-ups or short-term management of self-limited conditions.* These are likely to involve somewhere between two and six sessions over a period of less than six months, and many are unlikely to require the presence of a primary care physician. Examples of applications

falling into this category include neurologic work-up for headaches, management of complicated pregnancy, and oncologic supervision of a short-term chemotherapy regimen.

7) *Chronic disease management for conditions requiring a specialist not available locally.* These applications are more open-ended in their time requirements, and would generally involve a specialist and the patient, with no need for the primary care physician to be present. Examples of such applications would include a physiatrist or physical therapist involved in rehabilitation of a chronic pediatric disability, a nephrologist managing dialysis, brief psychotherapy, and neurologic management of Parkinson's disease or multiple sclerosis.

8) *Transmission of medical data.* This category could involve transmission of EEG or EKG by facsimile or modem. Also falling into this classification would be the transmission of historical information, results of lab studies (e.g., noninvasive blood chemistries from nursing home to clinic), and other clinical data.

9) *Public health and patient education.* Telemedicine might be used to provide patients with information about their condition, to allow physical therapists to describe rehabilitation exercises, or for education of groups of women with high-risk pregnancies. Some public health disaster relief activities would be included in this category.

The taxonomy proposed here focuses on general applications, processes of care, and not specialties or conditions. This has the advantage of simplifying the study of the effects of telemedicine. For example, in examining the cost-effectiveness of telemedicine systems overall, it might be of greater value to ask whether chronic disease management via telemedicine is cost-effective rather than to look individually at disorders like diabetes, congestive heart failure, and multiple sclerosis.

Similarly, the use of these categories is conceptually simpler than analysis of data by specialty. Endocrinologists, for example, engage in a number of different activities that might fall into several categories of this taxonomic scheme. These may vary significantly insofar as they represent an efficient use of the specialist's time. A broader perspective on telemedicine applications also is more likely to yield generalizable findings, and reduces the risk of having some cells that have too few data for analysis.

3. Summary of the Analytic Framework

The conceptual framework consists of three major dimensions or levels of analysis. The first deals with the adequacy of the basic technology, the second involves the medical effectiveness of specific applications, and the third treats the appropriateness of various applications. At present there exist insufficient data upon which to base conclusions regarding the cost effectiveness of telemedicine, and so we have not made this a part of our model. Research on the costs and economic impact of telemedicine is important, however, and there is a pressing need for research into the effects of telemedicine on the broader health care system. The dimensions of the proposed framework, which are discussed in detail below, are as follows:

1) *Adequacy of the technology*
   a. Factors affecting input of data
      1. Source of the data
      2. Speed of the equipment
      3. Image resolution and the input equipment
      4. Data compression and pretransmission image modifications
   b. Factors affecting throughput
      1. Nature of the telecommunications medium
      2. Bandwidth
   c. Factors affecting output
      1. Image resolution and the video display equipment
      2. Image manipulation and enhancement
2) *Medical effectiveness*
   a. Narrowing the scope of evaluation
      1. Conditions to be used as indicators of effectiveness
      2. Criteria for selection of effectiveness indicator conditions
   b. Establishing minimal levels of diagnostic accuracy
      1. Policy decisions involved in setting a level of diagnostic accuracy
3) *The appropriateness of telemedicine applications*
   a. Appropriate use of the technology within the health care system
   b. Appropriate use of the technology within specific applications

A detailed discussion of the analytic framework may be found in Report 1. In our earlier work, we recommended a relatively rigorous approach to assessing the sensitivity and specificity of telemedicine diagnosis. Subsequent experience with the technology suggests that, at least for most applications currently available, such an approach is unnecessary. Even given the paucity of research on effectiveness, sufficient evidence exists to suggest that the use of telecommunications technology for most routine clinical consultative purposes is acceptable.

Nevertheless, many new applications are being developed and it would be advisable to evaluate them thoroughly prior to implementing them on a wide scale. We suggest that the general strategy we outlined in Report 1 represents a reasonable method of approaching the task. Furthermore, it seems appropriate to study current telemedicine applications in this manner so that we may acquire a clear understanding of the effectiveness of telemedicine *vis à vis* traditional medical care.

CHAPTER 5

PAYMENT POLICY, UTILIZATION REVIEW, AND QUALITY ASSURANCE

A. PAYMENT POLICY: SUMMARY OF RECOMENDATIONS

Although the research literature on the effectiveness of clinical telemedicine is sparse, other data suggest that to proceed with reimbursement of some telemedicine services would be reasonable. In Report 3 we suggested possible telemedicine applications that might be covered by Medicare, and addressed a number of options for payment methodology. The issue is complex, and will require extensive research after policy decisions are made in order to refine the process. Regardless of the direction taken by HCFA, it would be advisable to conduct a large-scale, cross-cutting evaluation, beginning with baseline data to be obtained before coverage changes are made and designed to assess utilization, costs, outcomes, and any unanticipated consequences of the policy decision during the first several years after a policy is established.

In accordance with the taxonomy of applications discussed earlier, we recommended that telemedicine applications that are widely accepted as effective could be covered. The second category, applications that are probably effective, but with unknown effects on the health care system, could also be covered, but consideration might be given to some restrictions of coverage. The third category, applications that require basic research, should be considered on a case-by-case basis. In many instances, the technologies involved (e.g., robotic surgery) are clearly experimental, and ought not to be covered. A good deal of research must be done on most of these applications, demonstrating safety and effectiveness, before a decision is made to cover them.

Restrictions on coverage could be used, should HCFA decide that such an approach would be advisable. Thus, coverage might be limited to certain geographic areas (e.g., rural and frontier), to certain institutions (e.g., those willing to participate in data collection to permit further study of telemedicine), or to certain applications. The primary purpose of restricting coverage would be to limit expenditures while providing more time to study the impact of telemedicine on Medicare, and on the health care delivery system.

In Report 3, we discussed a number of approaches to payment. For more detail, the reader should refer to that manuscript. In general, it appears that fee-for-service payment to providers is the most viable way to deal with outpatient consults. The most efficacious way to handle this would probably be to establish a set of procedure codes reflecung the intensity (i.e., brief, intermediate, comprehensive) and nature (e.g., initial consult or followup) of services, and to establish fees for each code. For inpatient telemedicine services, a charge might be bundled into prospective payments for specific DRGs. Report 3 discusses other aspects of payment, including capitation, competitive contracting, and facility fees.

B. UTILIZATION REVIEW: SUMMARY OF RECOMMENDATIONS

Utilization review (UR) might be conducted for procedures and applications conducted by telemedicine for several reasons. Telemedicine is a new technology, and we have a great deal to learn about its efficacy and cost effectiveness. Past experience has demonstrated a tendency for new technologies to be overutilized. Further, because telemedicine is a new technology, there is a good deal of uncertainty about the range of appropriate and inappropriate applications. This uncertainty

creates a potential for either intentional or unintentional misuse, which could have significant implications for the quality of patient care and for health care expenditures.

At this point, there is no evidence that overutilization of telemedicine has occurred. To the contrary, given the low patient volumes to date, it is much easier to make the argument that telemedicine is being underutilized. The purpose of utilization review should be to assess problems in use, whether they involve overuse, underuse, or inappropriate utilization. Telemedicine is no more likely to be abused than any other medical technology, but prudent planning requires some preparation for the study of utilization patterns.

It is possible to use utilization review in a punitive manner, as a kind of sanction applied when one is concerned about overuse of services. While it clearly has an appropriate regulatory role, it was the suggestion of the advisory panel that UR should be conducted so that it has a facilitating, educational role. When used properly it may improve the delivery of health care.

A detailed discussion of utilization review may be found in Report 3. Here we will note only that such measures as pre-authorization of telemedicine services seem inadvisable. Retrospective review may be the most reasonable and effective way to assess the appropriateness of telemedicine services. We recommend the development of empirically-derived utilization guidelines, which we see as a variation on the theme of practice guidelines (Woolf, 1990, 1992, 1993), for different telemedicine applications (e.g., followup, triage). Such guidelines could facilitate UR activities by providing a standard against which use of telemedicine might be measured. Properly designed, practice guidelines might help to identify underuse of telemedicine, as well as overuse. For example, the charts of a sample of patients who did not get a telemedicine referral could be reviewed with reference to appropriate guidelines. This use of practice guidelines for utilization review could be undertaken by practitioners, institutions, or payers.

The kind of guidelines that might be developed, like the taxonomic scheme described previously, would not be primarily disease- or specialty-specific. Instead, the focus for guidelines should be on more general processes of care. There would thus be guidelines for the use of telemedicine in emergency trauma situations, medical-surgical followup, or complicated pregnancies. Some systematized set of procedures would also be warranted for periodic brief follow-up consults with patients having chronic disorders like chronic obstructive pulmonary disease, diabetes, or end-stage renal disease. To the extent possible, telemedicine practice guidelines should make explicit the situations in which the use of telemedicine is indicated, and the frequency and intensity of services appropriate for those situations. It should be understood that these would be general guidelines, suggesting a range of service utilization that would be reasonable. More specific indications for the use of telemedicine in individual cases would be a function of the diagnosis and clinical condition of any given patient, and these would not be covered by telemedicine practice guidelines.

C. QUALITY ASSURANCE: SUMMARY OF RECOMMENDATIONS

Quality assurance activities that focus on telemedicine services are rather different from QA applied to a specific surgical procedure (e.g., cholecystectomy) or medical intervention. Telemedicine is not a treatment *per se,* but is a medium through which medical care can be provided. Furthermore, at least at present, the number and kinds of treatments that can be provided via telemedicine are quite limited. Telemedicine is valuable primarily for diagnosis, consultation, and triage or emergency evaluation. It may be used for followup medical care, especially for routine postoperative appointments or medication checks.

It thus makes little sense, in quality assurance, to compare the effectiveness of telemedicine with the effectiveness of conventional medical care for the treatment of specific diseases or conditions. Telemedicine may provide a mechanism by which a patient can consult with a cardiologist who receives a transmission of the patient's echocardiogram, but cardiac catheterization (and a host of other procedures) cannot be done by telemedicine. It therefore is important to approach QA activities for telemedicine from a different angle.

In Report 3, we recommended an approach to QA activities that is based on general processes of care delivery, such as urgent care, chronic illness management, and diagnostic consultation. We recommended process and outcome research in order to assess the quality of care provided through telemedicine.

CHAPTER 6

TECHNICAL ADVISORY PANEL REVIEW OF THE PROJECT

A. GENERAL OVERVIEW

On 20 July 1994, a meeting of a technical advisory panel was held at the Office of Research and Demonstrations of the Health Care Financing Administration in Baltimore. Panel members, who had been chosen for their expertise in telemedicine or relevant policy issues, were given an opportunity to review Reports 1 and 2, and a preliminary draft of Report 3. The purpose of the meeting was to establish a forum in which the reports, and policy recommendations made by the Center for Health Policy Research, could be critiqued and discussed in some depth. The suggestions of the panel members were incorporated into a revision of Report 3, and have influenced this final discussion of our findings.

The meeting was divided into six segments, addressing the following issues:

- Current status of telemedicine: safety and medical effectiveness
- Current status of telemedicine: access to care and implications for health care delivery
- Utility of the taxonomy and analytic framework
- Approaches to reimbursement and payment options
- Possible abuses of telemedicine, quality assurance, and utilization review
- Further research needs

B. PARTICIPANTS IN TECHNICAL ADVISORY PANEL MEETING

The following individuals participated in the meeting of the advisory panel:

- Laura N. Adams, Medical College of Georgia
- Rashid Bashshur, Ph.D., University of Michigan
- Paul Ginsburg, Ph.D., Physician Payment Review Commission
- Aubry Godfrey, M.D., Blue Cross/Blue Shield of Texas
- Carole L. Mintzer, Federal Office of Rural Health Policy
- Douglas A. Perednia, M.D., Oregon Health Sciences University
- Jim Reid, P.A., Eastern Montana Telemedicine Project
- Elliot J. Sandberg, M.D., Denver V.A. Medical Center

Present from the Center for Health Policy Research:

- Jim Grigsby, Ph.D.
- Robert E. Schlenker, Ph.D.

Present from the Office of Research and Demonstrations, Health Care Financing Administration:

- Michael Hupfer
- Cindy Mason

CHAPTER 7

TELEMEDICINE: RESEARCH RECOMMENDATIONS

A. RECOMMENDATIONS FOR AN EVALUATION STRATEGY FOR TELEMEDICINE

1. General Introduction

Few empirical data exist concerning telemedicine. From the perspective of carefully designed research, except for teleradiology and telepathology, we know very little about the costs, effects, and effectiveness of telemedicine. Nonetheless, all indications are that both the private sector and the federal government are aggressively engaged in the proliferation of telemedicine. While it appears that many applications of clinical telemedicine have the potential to provide quality health care to persons now lacking access, many programs that are under consideration or presently being tested are intended to provide services to persons outside underserved segments of the population.

The technology utilized in telemedicine is relatively complex and constantly changing. New technologies are emerging, many from unrelated fields, and there is every reason to believe that they will become integrated into telemedicine. This development and convergence of technologies will require that significant resources go into technology assessment, in order to insure medical effectiveness.

The extent to which Medicare should become involved in technology assessment is unclear. As a rule, HCFA has relied on the results of technology assessment without funding the clinical trials that might establish medical effectiveness. Recently, however, Buto (1994) suggested the possibility that HCFA might become more involved in the process of making technological innovations more readily available to Medicare beneficiaries. In particular, she argued that "any changes should provide more options for providers and patients and greater flexibility for the Medicare program to revise coverage policy. Two alternative meet these goals: (1) broader use of limited coverage approaches; and (2) a clinical research fund or set-aside approach" (p. 139).

Although she was not addressing telemedicine specificially, Buto's remarks could be extended to telemedicine. This would require a policy shift by HCFA, since in the past the onus for demonstrating effectiveness of a technology has generally been on the manufacturers and early user-investigators.

Health services research falls more clearly in HCFA's purview. Medicare must be concerned with the effects of widespread proliferation and integration of telemedicine technologies into the health care system. There is currently a dearth of information on the effects of telemedicine on such matters as costs, access, practice patterns, and patient management, and policy development would be considerably enhanced with data on these subjects. Other evaluation topics that would help inform Medicare policy makers include the areas of payment, utilization, appropriateness, and quality assurance.

2. New Technologies

Given the rate of development of new technologies and applications, the state of the art in telemedicine can be expected to change rapidly. Robotics already plays a role in the use of microscopes by pathologists, and further developments will surely be introduced. The Advanced Research Projects Agency is considering investigating the use of telerobotic laparoscopic surgery, with

surgery performed remotely on patients by surgeons who manipulate instruments from a distant site. Likewise, virtual reality technology (Fuchs, Pizer, Creasy, et al., 1988) is rapidly gaining entry into medicine. Another burgeoning field is the use of specialized applications of artificial intelligence. Knowledge-based systems (KBSs) and simulated neural networks already have demonstrated their utility in a number of situations, including radiologic detection of breast carcinoma and diagnosis of acute myocardial infarction (Baxt, 1991a, 1991b; Dawson, Austin, and Weinberg, 1991; Furlong, Dupuy, and Heinsimer, 1991). In at least one case, a computerized neural network showed greater accuracy in diagnosis of MI than did cardiologists. Considerable other work is currently in progress using neural networks for a range of purposes, including the prediction of medical outcomes.

B. HEALTH CARE SYSTEM EFFECTS AND IMPLICATIONS FOR MEDICARE

1. Medical Effectiveness of Telemedicine

A range of opinions exists regarding the effectiveness of telemedicine. Some assert that it is effective across the board, while others are less sanguine. Many of the concerns expressed by physicians who have used telemedicine have to do with diagnostic accuracy given the available equipment. Although on the face of it, clinical consultation using telemedicine appears to be effective, the literature provides little support. Physicians representing a range of specialties have expressed some concerns, and it is clear that lingering questions will be settled only by means of carefully designed and conducted research.

For nearly every specialty, it is possible to find some area(s) about which providers will report uncertainty. Compressed video may make the evaluation of gait or tremor difficult or impossible for neurologists. The inability to feel the carotid arteries may limit the utility of telemedicine in some cases for cardiologists or neurologists, who must then rely on the skill of the examiner at the remote location. Some ophthalmologists have indicated that they are not entirely comfortable with the quality of images of the fundus, while dermatologists expressed concern about the lighting and resolution necessary to view skin lesions accurately. In psychiatry, there is uncertainty about whether the quality of rapport will be adequate with patients in a video conference, and some psychiatrists questioned whether they could track nonverbal behavior as well as they otherwise might. Overall, physicians using telemedicine believe it to be of generally good quality, but it is clear that many questions need to be examined. Research in these areas will likely be conducted, but broad studies of medical effectiveness, particularly comparative effectiveness among different technologies, will be needed on an ongoing basis as technology evolves.

2. Cost-Effectiveness of Telemedicine

In the past, the introduction of new technologies has often been accompanied by claims of efficacy and cost-effectiveness. Most technological advances, however, have increased the costs of medical care. The End Stage Renal Disease Program was a clear illustration of the unanticipated expenses that might ensue from widespread expansion of coverage for certain interventions. Experience with that program demonstrates the need for a systematic program of research surrounding the introduction of new health care technologies.

As noted previously, there are very few data concerning the costs and cost effectiveness of telemedicine systems. As technology advances, the cost of upgrading currently available equipment may well remain stable or even decrease. However, new kinds of equipment will be introduced, often at considerable expense, and the need for such equipment may not always be clear. As telemedicine becomes integrated into everyday health care, staffing patterns will change. For example, there may

be an emphasis on the use of nurse practitioners and other non-physician providers in rural areas, with physician backup via telecommunications links. Managed care may come to play a large role in the utilization of telemedicine. All of these factors will influence the costs and cost-effectiveness of telemedicine relative to conventional approaches. The broader integration of telemedicine services into the health system thus is likely to affect staffing patterns and associated costs, as well as the use of institutional and noninstitutional health care services. It is important to consider not only how these services may affect the accessibility and quality of care, but also the consequent utilization and cost impacts.

Because telemedicine is a relatively new phenomenon, only now beginning a phase of proliferation, the costs of its implementation, both short- and long-term, are likely to change significantly over the next decade. Data on cost-effectiveness collected now may be completely unrelated to data on cost-effectiveness in five years. Thus, telemedicine appears to be an area where a periodic updating of information regarding medical effectiveness and cost-effectiveness will be necessary.

3. Integration of Telemedicine into Comprehensive Health Care Systems

Most telemedicine projects to date have had narrowly defined target populations and applications. If telemedicine truly lives up to the claims of its proponents, however, it will eventually become integrated into the overall health care delivery system. The success of telemedicine will thus be measured by the extent to which it is no longer a stand-alone application. Its evaluation at that time would clearly be a different matter than its assessment while it is still a circumscribed delivery system with low volumes of patients.

Bashshur (1980) has argued for the need to demonstrate the capabilities of telemedicine systems with a "noncaptive, general client population." He proposed a two-stage process which illustrates some components that would be important in a more comprehensive evaluation approach. The first stage is descriptive and documentary, addressing the configuration, design, and objectives of the system, along with associated factors such as acceptance by providers and patients (Bashshur, 1978). The second stage is analytic and utilizes a two-dimensional matrix. The first dimension covers the structure of the system (target population, organizational base, provider mix, and communication medium), while the second dimension consists of a variety of process, content, and outcome variables.

C. RECOMMENDATIONS FOR TELEMEDICINE RESEARCH

1. General Introduction

In arriving at recommendations for research, we began by assuming that HCFA is presently committed to a program of establishing coverage policy for at least some telemedicine applications. We further assume that the Office of Research and Demonstrations intends to continue its present policy of funding a series of multi-year demonstration projects, and that HCFA is attempting to coordinate the research activities of the agency with those of other agencies, perhaps including the Office of Rural Health Policy (ORHP), the National Telecommunications Infrastructure Administration (NTIA), the Rural Electrification Administration (REA), and the Congressional Office of Technology Assessment (OTA).

Given these assumptions, we can classify research on telemedicine into one of two broad categories: 1) issues related to the implementation of policy, and 2) more general issues related to

costs, effects, and effectiveness. Before discussing these categories, we first highlight more general issues in telemedicine research.

2. General Issues in Federally Funded Telemedicine Research

The agencies currently funding research in telemedicine are doing so at the level of individual institutions. For HCFA and ORHP, these are demonstration and evaluation projects. For REA and NTIA, little or no evaluation of the effectiveness of telemedicine is currently involved.

When evaluation is conducted by each individual program, certain difficulties are typically encountered. First, the research design, methodology, and data analysis are only as good as the investigators involved. Although grant applications for certain demonstration projects may be interesting, it is likely that relatively few include a good evaluation design. This may be the case especially for rural programs with limited access to good health services researchers. Whether the results of a study (as an evaluation or a demonstration) will justify its time and expense for HCFA is then unclear until after the project is completed. More importantly, when telemedicine programs are evaluated in isolation, the findings may not be generalizable to other programs.

This issue has been partially addressed by the Request for Proposals issued by the Health Resources Services Administration to develop a set of instruments that could be used more generally to assess telemedicine programs. Uniform instruments, however, may yield misleading data if different telemedicine programs have markedly different evaluation designs, or if the sample populations are quite different. One may, under those circumstances, be tempted to assume that the data are comparable across sites, when in fact they are derived by very different means and drawn from very different samples. In such a case, the findings from any given program may not be generalizable to other programs.

We recommend a solution to this problem that would involve separating the implementation and evaluation components of the various demonstration projects. Using this approach, several facilities would be funded to set up and operate telemedicine programs with particular specifications. Money might be included in the budget for evaluation of certain applications unique to individual sites, but the overall evaluation of the program would not be the responsibility of any single demonstration facility. Instead, grant or contract money would be made available to other investigators for a cross-cutting evaluation of all demonstration projects. Proposals would be solicited, and awards made to one or more institutions that would have the responsibility for the overall evaluation of the demonstration projects, or for evaluation of certain components of those projects. Thus, one institution might examine costs, cost-effectiveness, and other economic effects, while another might be concerned primarily with medical effectiveness and the effects of telemedicine on the health care system.

The described approach would have several clear advantages. It would: 1) assure uniformity of data and data collection protocols; 2) assure consistent design across sites, including sampling and collection of control/comparison data; 3) provide larger numbers of patients for analysis; 4) permit a broader range of patient demographic and clinical characteristics; and 5) yield results that might permit generalizations beyond the sites involved. In addition, this would permit HCFA to use the different sites to test hypotheses regarding payment and utilization.

3. Medical Effectiveness

Whether or not to fund research on medical effectiveness is a policy question for HCFA, as discussed previously. While a reasonable argument can be made for this position (Buto, 1994), it is

also reasonable to expect manufacturers, vendors, and users to bear some of the responsibility for this endeavor.

In performing research on medical effectiveness, we recommend the use of some approach such as the analytic framework discussed in Report 1 under this contract (Grigsby, Kaehny, Schlenker, et al., 1993). Ideally, both telemedicine and conventional medical care would be compared with some "gold standard" such as a pathology diagnosis. The relative accuracy of the two methods could then be compared using receiver operating characteristic (ROC) curves. When no gold standard is available for comparison, concordance rates between conventional and telemedicine diagnoses can be calculated. The difficulty with this approach is that conventional methods are likely to become the *de facto* standard despite the fact that conventional diagnoses are not accurate 100% of the time.

There are a wide range of technologies and applications that might be evaluated. The video and audio resolution required for certain applications (e.g., auscultation, dermatologic lesions) have not yet been established. It is likewise unclear what equipment is necessary to support various applications. Conrath et al. (1977) compared still images with moving video (color and black and white) and telephone, finding no significant differences. A study of that kind could be conducted again using current technology, and focusing on establishing minimal standards for various applications. One might find, for instance, that static images are adequate for most purposes. Such a finding would have clear implications for line access charges, capital expenditures, and scheduling of consults. If only still images were required (as is probably the case for dermatology), a store and forward system might be adequate, at least for a specific application.

4. Health Services Research: Costs, Access, Acceptance, and Related Issues

We presently only can speculate about the effects of telemedicine on the quality of medical care and on the health care system. Although it seems reasonable to approve coverage for many telemedicine applications, there are many unknowns. No single demonstration project can answer all of these questions. It will be important to study a range of programs, both HCFA- or ORHP-funded demonstrations, and others that are operating without federal support. Cooperation with this approach might be facilitated by establishing conditions for participation in reimbursement that would require collection of standard data.

Studies funded to analyze these issues should be designed to collect data over a period of two or three years from a minimum of eight to ten sites. Given the current situation, the use of claims data on telemedicine would be impossible, so the studies should involve prospective research and primary data collection. Randomized clinical trials may be difficult to carry out, but should be conducted when possible. When randomized studies are not practical, careful attention should be given to the collection of data from an appropriate comparison group. A case control design might be used, matching subjects on such factors as severity of illness, availability of medical care, socioeconomic status, or other relevant covariates, using either historical or prospective data collection.

Although studies of diagnostic accuracy might require the analysis of patient data by specialty or medical condition, studies of health services issues might best be done by grouping data by general categories of telemedicine application. This would be consistent with the taxonomy proposed in Report 2. In this way, patient-provider contacts could be classified into such categories as urgent care, triage, diagnostic consultation, or management of chronic illness. The management of chronic illness, for example, could include consultation with specialists for patients with such diverse conditions as diabetes, chronic obstructive pulmonary disease (COPD), multiple sclerosis, congestive heart failure, or end stage renal disease. By analyzing data by these broad categories rather than

single specialties or diagnoses, one gains the ability to assess the effectiveness of telemedicine across diagnoses, but for similar purposes. One also avoid the problems associated with too few subjects per cell in analyses of specific diseases. This is particularly important at this stage of the development of telemedicine, when patient volumes remain relatively low.

Studies of costs and cost effectiveness require special attention to design. Cost-effectiveness analysis (CEA) and cost benefit analysis (CBA) are most commonly conducted with respect to a specific treatment or intervention. For all practical purposes, telemedicine encompasses all possible conditions. Thus sampling, data collection, assessment of benefits, and many other research components must be done rather differently than if one were studying, for example, outcomes of coronary artery bypass grafts versus angioplasty. CBA in particular seems conceptually difficult given this situation. Economic models that rely primarily on projections are unlikely to be helpful.

CEA, however, is also difficult to perform properly in the case of telemedicine. A common argument in favor of telemedicine, for example, is that it saves the time and expense of travel for residents of rural areas who must otherwise go to an urban medical center to see a specialist. While this often may be seen as a benefit by patients, it frequently is the case that they may see the trip as an opportunity to take care of necessary errands or perform other tasks that cannot be taken care of in their own community. It could therefore be problematic to consider elimination of a trip as a benefit in all cases. It may also be difficult to determine whether a telemedicine contact is a substitute for another service, or if it provides additional medical care. Thus it may be unclear whether the alternative to which telemedicine is compared is conventional care, or no care, or some other possibility (e.g., a trip to the local chiropractor).

Finally, it is important to study several levels of analysis for the study of costs. Telemedicine, for example, might be cost-effective for patients, yet produce greater expenditures for Medicare. In such a situation, the relative benefits of telemedicine are a legitimate subject for debate by parties with differing interests, but it is important for the various participants in the health care system to obtain information regarding the possible costs of the system to them. HCFA may decide to provide coverage for clinical telemedicine, but in doing so the agency must also be able to anticipate the effect of such a policy decision on costs.

5. Research on Payment Policy and Utilization

In certain respects, the fundamental issue facing HCFA is how to pay for telemedicine. The questions that must be addressed include the following.

1) What programs, or kinds of programs, should be reimbursed?
2) What providers should be reimbursed?
3) How much should be paid for a consult?
4) How should payment be made?
5) Should a facility be somehow reimbursed for the use of the equipment?
6) How should a facility fee be paid?
7) For inpatient consults, should reimbursement be on a fee-for-service basis, or bundled?

In conjunction with our current contract, we were also asked to address the issues of quality assurance and utilization review. In that context we recommended the development of a set of telemedicine utilization guidelines that could be used as a frame of reference for judging the appropriateness of telemedicine services. Such guidelines, patterned after the practice guidelines being developed for certain specific disease conditions (only more streamlined and program-oriented), would provide direction regarding when telemedicine should and should not be used. They might,

for example, allow one to determine whether an emergency care consult should or should not have been obtained.

HCFA has an interest in research regarding the areas of payment, coverage policy, and utilization guidelines. With respect to payment, it might be desirable to develop two or three approaches, to implement these on a pilot basis in several demonstration programs, and to study the effects of different coverage and payment schemes on utilization and costs. The data obtained could be used to modify or refine different approaches, and to determine their viability and acceptability both to HCFA and to the providers.

In a large scale, three to five year cross-cutting study of several telemedicine sites, one could acquire the data needed to establish and to refine utilization guidelines. For purposes of understanding variability in utilization patterns, it would be most beneficial to have several participating sites that varied markedly in their characteristics. For example, although rural telemedicine is the current focus of most funding, the use of telemedicine in a large managed care program would be useful to evaluate. One might assume *a priori* that such a program would attempt to limit utilization in order to hold down costs. The inclusion of a program such as this would help to establish a lower bound for utilization, given that underuse may itself result in problems with quality of care.

APPENDIX A

REFERENCES

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